

Docket No.: 0760-0346PUS1
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Hiroshi TAKAHASHI et al.

Application No.: 10/533,878

Confirmation No.: 9660

Filed: November 21, 2005

Art Unit: 1642

For: METHOD OF EXAMINING CANCER CELLS
AND REAGENT THEREFOR

Examiner: L. B. Goddard

REQUEST FOR REFUND
(IMPROPER CHARGE OF DEPOSIT ACCOUNT)

MS 16
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I. REFUND REQUEST

This is a request for a refund with respect to the charge to Deposit Account 02-2448 shown on the statement for the month of February 2008 for the above-identified

☒ application ☐ patent

☒ A copy of the monthly statement in which the error referred to occurs, accompanies this request.

II. FEES CHARGED FOR WHICH REFUND REQUESTED

	<u>AMOUNT OF REFUND REQUESTED</u>
<input type="checkbox"/> filing fee	_____
<input type="checkbox"/> search fee	_____
<input type="checkbox"/> examination fee	_____
<input type="checkbox"/> surcharge for filing the basic filing on a date later than the filing date of the application (37 C.F.R. § 1.16(e))	_____
and/or	
<input type="checkbox"/> surcharge for filing the oath or declaration on a date later than the filing date of the application (37 C.F.R. § 1.16(e))	_____
<input checked="" type="checkbox"/> extension of term	
<input type="checkbox"/> first month	_____
<input checked="" type="checkbox"/> second month	<u>\$230.00</u>
<input type="checkbox"/> third month	_____
<input type="checkbox"/> fourth month	_____

- | | | |
|--------------------------|----------------------------------|-------|
| <input type="checkbox"/> | excess claims | _____ |
| <input type="checkbox"/> | issue fee | _____ |
| <input type="checkbox"/> | petition fee | _____ |
| <input type="checkbox"/> | patent maintenance fee | _____ |
| <input type="checkbox"/> | first maintenance fee | _____ |
| <input type="checkbox"/> | second maintenance fee | _____ |
| <input type="checkbox"/> | third maintenance fee | _____ |
| <input type="checkbox"/> | patent maintenance fee surcharge | _____ |
| <input type="checkbox"/> | Other: | _____ |
| | | _____ |
| | | _____ |

TOTAL REFUND REQUESTED

\$230.00

III. EXPLANATION OF WHY CONTESTED CHARGE IS IN ERROR

Office Action dated 11/02/07 (PTOL-326) states “period for reply is set to expire 3 months or 30 days, whichever is longer, from the mailing date of this communication”. A response to restriction was submitted on February 4, 2008 (Monday) within the three months time period and therefore, no extensions fees are due.

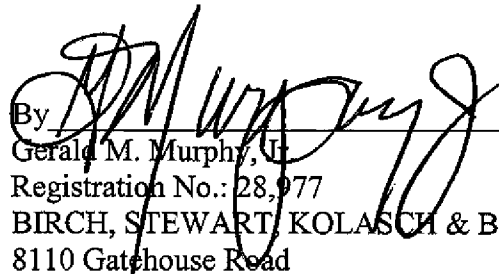
IV. MANNER OF REFUND

Please make refund by crediting Account No. 02-2448.

We respectfully request that the attached copy of this letter be returned to us with an indication that the credit has been processed.

Dated: MAR 07 2008

Respectfully submitted,

By 
Gerald M. Murphy, Jr.
Registration No.: 28,977
BIRCH, STEWART, KOLASCH & BIRCH, LLP
8110 Gatehouse Road
Suite 100 East
P.O. Box 747
Falls Church, Virginia 22040-0747
(703) 205-8000
Attorney for Applicant

Attachment(s)

Deposit Account Statement

Requested Statement Month: February 2008
Deposit Account Number: 022448
Name: BIRCH STEWART KOLASCH & BIRCH
Attention:
Street Address 1: 8110 GATEHOUSE ROAD
Street Address 2: SUITE 500 EAST
City: FALLS CHURCH
State: VA
Zip: 22042
Country: UNITED STATES

DATE	SEQ	POSTING REF TXT	ATTORNEY DOCKET NBR	FEE CODE	AMT	BAL
02/01	1	10831450	2080-3253	1252	\$340.00	\$244,585.00
02/01	454	2538547	5389-0116US1	7205	\$100.00	\$244,485.00
02/01	455	2538547	5389-0116US1	7208	\$200.00	\$244,285.00
02/01	725	60898109	4614-0215PUS1	8007	\$20.00	\$244,265.00
02/01	755	60898718	0104-0612PUS1	8007	\$20.00	\$244,245.00
02/01	1410	11023502	4795-0125PUS1	1252	\$460.00	\$243,785.00
02/01	1933	10518926	1422-0655PUS1	1252	\$460.00	\$243,325.00
02/01	2346	PCT/US08/52609	5998-0518WO2	1601	\$300.00	\$243,025.00
02/01	2347	PCT/US08/52609	5998-0518WO2	1703	\$247.00	\$242,778.00
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02/01	2392	12023566	0951-0219PUS1	1111	\$510.00	\$238,641.00
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02/01	3697	10528051	0171-1190PUS1	8001	\$12.00	\$233,709.00

02/28	6638	12038738	2411-0111PUS1	1201	\$420.00	\$249,696.99
02/28	6636	12038738	2411-0111PUS1	1111	\$510.00	\$249,186.99
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02/28	6749	10527594	1173.1027P	1615	\$250.00	\$248,726.99
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02/28	268	09813112	3782-0124P	1806	\$180.00	\$242,486.99
02/28	269	11984028	1063-0126PUS1	1051	\$130.00	\$242,356.99
02/28	271	11168418	0171-1222PUS1	1801	\$810.00	\$241,546.99
02/28	272	11168418	0171-1222PUS1	1252	\$460.00	\$241,086.99
02/28	273	11258120	2519-0208PUS1	1252	\$460.00	\$240,626.99
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02/28	275	10377694	2091-0266P	1252	\$460.00	\$239,656.99
02/28	276	09790660	1794-0133P	1401	\$510.00	\$239,146.99
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02/28	97	11990987	2360-0485PUS1	1633	\$210.00	\$236,766.99
02/28	98	11990987	2360-0485PUS1	1642	\$410.00	\$236,356.99
02/28	99	11990987	2360-0485PUS1	8021	\$40.00	\$236,316.99
02/28	5	10589953	5000-0190PUS1	8021	\$40.00	\$236,276.99
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02/28	42	10555436	3560-0149PUS1	1615	\$300.00	\$235,936.99
02/28	43	10555436	3560-0149PUS1	1251	\$120.00	\$235,816.99
02/28	2	10533878	0760-0346PUS1	2252	\$230.00	\$235,586.99
02/28	10216	11795572	3782-0304PUS2	1464	\$130.00	\$235,456.99
02/28	10245	10687879	2428-0125P	1501	\$1,440.00	\$234,016.99
02/28	10248	10687879	2428-0125P	8001	\$12.00	\$234,004.99
02/28	10247	10687879	2428-0125P	1504	\$300.00	\$233,704.99
02/28	10418	10515297	3749-0104PUS1	1501	\$1,440.00	\$232,264.99
02/28	10419	10515297	3749-0104PUS1	1504	\$300.00	\$231,964.99
02/28	10420	10515297	3749-0104PUS1	8001	\$12.00	\$231,952.99
02/28	321	11991073	3939-0162PUS1	1631	\$310.00	\$231,642.99
02/28	326	11991075	3939-0163PUS1	1631	\$310.00	\$231,332.99
02/28	327	11991076	3939-0161PUS1	1631	\$310.00	\$231,022.99
02/28	2	11886449	2081-0131PUS2	2617	-\$65.00	\$231,087.99
02/28	3	11886449	2081-0131PUS2	2633	\$100.00	\$230,987.99
02/28	4	11886449	2081-0131PUS2	2642	\$200.00	\$230,787.99





UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,878	11/21/2005	Hiroshi Takahashi	0760-0346PUS1	9660

EXAMINER	
GODDARD, LAURA B	

ART UNIT	PAPER NUMBER
1642	

NOTIFICATION DATE	DELIVERY MODE
11/02/2007	ELECTRONIC

2292 7590 11/02/2007
BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

m. rogers
DOCKETED
Restriction
2-2-08

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/533,878	TAKAHASHI ET AL.	
	Examiner	Art Unit	
	Laura B. Goddard, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-7 and 10-16 is/are pending in the application.
- 4a) Of the above claim(s) 11,12,15 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-3,5-7,10,13 and 14 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/16/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The Election filed August 13, 2007 in response to the Office Action of July 13, 2007 is acknowledged. Applicant elected with traverse, the species of examination "(a) examining nucleic acids" and the HTLV-1 gene.

2. Applicants argue that by searching one group, the Examiner is necessarily searching the other group since the claims are closely related in subject matter and it would not be undue burden to search all of claims 1-3, 5-7, and 10-16 (p. 2).

The arguments have been considered but are not found persuasive because each species of examination of the cells isolated in the method of claim 1 require distinct method steps, reagents, assays, and criteria for success. Further, assaying for different species of nucleic acids requires different method steps, reagents, and criteria for success. Searching all of the groups with all of the different variables is not extensively overlapping, and would invoke a high burden of search. For these reasons, the restriction requirement is deemed to be proper and is therefore made FINAL.

Claims 1-3, 5-7 and 10-16 are pending. Claims 11, 12, 15, and 16 are withdrawn as being drawn to non-elected species. Claims 1-3, 5-7, 10, 13, and 14 are currently being examined.

Election/Restrictions

3. After a First Office Action, Applicants amended independent claim 1 on 4/16/2007 to recite several different species of cells. An additional restriction for species of cells is set forth below.

SPECIES ELECTION

4. This application contains claims directed to the following patentably distinct species of cells: **Elect ONE or a specific combination of cells from claim 1.**

The species are independent or distinct because each cell type has a different etiology, different structure, and different function, and expresses different proteins, all of which distinguish them as physiologically distinct tissues.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species.
MPEP § 809.02(a).

5. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.


6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura B. Goddard, Ph.D. whose telephone number is (571) 272-8788. The examiner can normally be reached on 7:00am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.




Laura B Goddard, Ph.D.
Examiner
Art Unit 1642



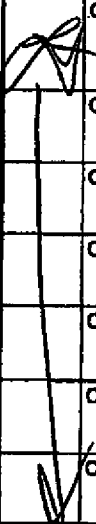
Approved for use through 03/31/2007. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO		Complete if Known			
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)		Application Number	10/533,878-Conf. #9660		
		Filing Date	November 21, 2005		
		First Named Inventor	Hiroshi TAKAHASHI		
		Art Unit	1642		
		Examiner Name	L. B. Goddard		
Sheet	1	of	2	Attorney Docket Number	0760-0346PUS1

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	AA*	US-8,008,002	12-28-1999	Bodey	
	AB*	US-20010000751-A1	05-03-2001	Schnitz et al.	
	AC*	US-20020009759-A1	01-24-2002	Terstappen et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ³
		Country Code ² -Number ² -Kind Code ² (if known)				
	BA	WO-95/24648-A1	09-14-1995	FODSTAD et al.		
	BB	WO-93/06117-A1	04-01-1993	The General Hosp. Corp.		
	BC	WO-01/18956-A1	03-22-2001	BANDER		

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 608. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. * CITE NO.: Those application(s) which are marked with an single asterisk (*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(ii)) because that application was filed after June 30, 2003 or is available in the IFW. ¹ Applicant's unique citation designation number (optional). ² See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			T ³
	CA	J E HARDINGHAM ET AL, "Immunobead-PCR: A Technique for the Detection of Circulating Tumor Cells Using Immunomagnetic Beads and the Polymerase Chain Reaction", Cancer Research, American Association For Cancer Research, August 1, 1993, pages 3455-3458, Vol. 53			
	CB	BRANDT B ET AL, "Isolation of Prostate-derived Single Cells and Cell Clusters from Human Peripheral Blood", Cancer Research, American Association for Cancer Research, October 15, 1996, pages 4556-4561, Vol. 15 No. 20			
	CC	BEROIS N ET AL, "Detection of Rare Human Breast Cancer Cells. Comparison of an Immunomagnetic Separation Method with Immunocytochemistry and RT-PCR", Anticancer Research, Hellenic Anticancer Institute, pages 2639-2646, Vol.17			
	CD	LUKE ET AL, "Detection of Breast Cancer Cells in Blood Using Immunomagnetic Bead Selection and Reverse Transcription-Polymerase Chain Reaction", Molecular Diagnosis, September 1998, pages 149-155, Vol. 3 No. 3			
	CE	SAKAGUCHI M ET AL, "Development of a sensitive, specific reverse transcriptase polymerase chain reaction-based assay for epithelial tumour cells in effusions", February 1999, pages 416-422, Vol. 79 No.3/4			
	CF	TAKAHASHI H ET AL, "Radioimmunolocalization of Hepatic and Pulmonary Metastasis of Human Colon Adenocarcinoma", Gastroenterology, Saunders, May 1988, pages 1317-1329, Vol. 96 No.5			
	CG	SUZUKI S ET AL, "Human lymphocytes activated by chimeric SF-25 monoclonal antibody induce apoptosis of HTLV-1 infected T-cell lines resistant against anti-Fas TNFalpha and IFNgamma", Blood, Vol. 92, No. 10, Suppl.1 Part 1-2, November 15, 1998, pages 248A			


Examiner Signature		Date Considered	10/24/07
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Birch, Stewart, Kolesch & Birch, LLP

GMM/TJS/g

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Application Number	10/533,878-Conf. #9660
				Filing Date	November 21, 2005
				First Named Inventor	Hiroshi TAKAHASHI
				Art Unit	1642
				Examiner Name	L. B. Goddard
Sheet	2	of	2	Attorney Docket Number	0760-0346PUS1

	CH	SUZUKI S ET AL, "Peripheral blood lymphocytes from patients with adult T-cell leukemia in remission induce apoptosis to HTLV-1 infected T-cell line by activation with chimeric SF-25 monoclonal antibody" November 15, 1999, page 88a, Blood Vol. 94, No. 10, Suppl. 1 Part 1	
	CI	SUZUKI S ET AL, "Human lymphocytes activated by chimeric kSF-25 monoclonal antibody induce apoptosis of HTLV-1 infected T-cell line" JOURNAL OF ACQUIRED IMMUNE DEFICIENCY SYNDROMES AND HUMAN RETROVIROLOGY, Vol. 20, No. 4, April 4, 1999, page A61	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

*Applicant's unique citation designation number (optional). *Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	10/24/07
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Birch, Stewart, Kotsch & Blum, LLP

GMM/TJS/tg